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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,339	09/27/2006	Tomoyuki Nakamura	2006_1605A	1266
513 7590 03/11/2009 WENDEROTH, LIND & PONACK, L.L.P. 1030 15th Street, N.W., Suite 400 East Washington, DC 20005-1503				
EXAMINER				
SWOPE, SHERIDAN				
ART UNIT		PAPER NUMBER		
1652				
MAIL DATE		DELIVERY MODE		
03/11/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/594,339

## Applicant(s)

NAKAMURA ET AL.

## Examiner

SHERIDAN SWOPE

## Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-27, 29 and 33-46 is/are pending in the application.
- 4a) Of the above claim(s) 3-27, 29, 33, 34 and 36-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 1108
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants' amendment of November 24, 2008, in response to the Action of August 22, 2008 is acknowledged. It is acknowledged that Claims 1, 2, and 35 have been amended. Claims 1-27, 29, and 33-46 are pending. Claims 3-27, 29, 33, 34, and 36-46 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 1, 2, and 35 are hereby reconsidered.

#### ***Priority***

The priority date granted for Claims 1, 2, and 35 is March 29, 2004, the filing date of JP 2004-096685, which disclosed the polypeptides of SEQ ID NO: 6, 10, and 14 as well as the genus of polypeptides having at least 90% identity to SEQ ID NO: 6.

#### ***Abstract-Objections***

The abstract is objected to for poor grammar; it appears to be a poor translation of a foreign document. It also exceeds 150 words.

MPEP 608.01(b) states:

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phrasology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

#### ***Claim Rejections - 35 USC § 112-Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons.

Claims 2 and 35 are rendered indefinite for improper antecedent usage. For each claim, the phrase "The polypeptide of claim 1" should be corrected to "The isolated polypeptide of claim 1".

***Claim Rejections - 35 USC § 112-First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Enablement**

Rejection of Claims 1, 2, and 35 under 35 U.S.C. 112, first paragraph/lack of enablement, for the reasons explained in the prior action, is maintained. In support of their request that said rejection be withdrawn, Applicants provide the following arguments. Claim 1 is now directed towards a polypeptide which consists of an amino acid sequence having at least 90% identity to SEQ ID NO: 6, retaining a consensus Arg-Gly-Asp motif, and having binding activity for  $\alpha\beta3$ ,  $\alpha\beta5$ , or  $\alpha9\beta1$  integrin. The present specification and Nakamura et al, 2000 provide enablement for such a polypeptide and therefore this rejection is overcome.

These arguments are not found to be persuasive for the following reasons. It is acknowledged that Claim 1 is so amended. However, neither the specification nor the prior art enable the skilled artisan to make and use any polypeptide having at least 90% identity to SEQ ID NO: 6, wherein the polypeptide binds to any protein having  $\alpha\beta3$ ,  $\alpha\beta5$ , or  $\alpha9\beta1$  integrin

activity. The family of integrins, including  $\alpha\text{v}\beta 3$ ,  $\alpha\text{v}\beta 5$ , or  $\alpha 9\beta 1$ , are structurally and functionally diverse (van der Flier et al, 2001). Claim 88 encompasses polypeptides capable of binding to any protein having any structure and any activity of any  $\alpha\text{v}\beta 3$ ,  $\alpha\text{v}\beta 5$ , or  $\alpha 9\beta 1$  integrin. The specification fails to enable the skilled artisan to make and use all such polypeptides without the undue burden of testing for binding to any protein having any structure and any activity of any  $\alpha\text{v}\beta 3$ ,  $\alpha\text{v}\beta 5$ , or  $\alpha 9\beta 1$  integrin.

For these reasons and those explained in the prior action, rejection of Claims 1, 2, and 35 are rejected under 35 U.S.C. 112, first paragraph/lack of enablement, is maintained.

#### **Written Description**

Rejection of Claims 1, 2, and 35 under 35 U.S.C. 112, first paragraph/written description, for the reasons explained in the prior action, is maintained. In support of their request that said rejection be withdrawn, Applicants provide the following arguments. Claim 1 is now directed towards a polypeptide which consists of an amino acid sequence having at least 90% identity to SEQ ID NO: 6, retaining a consensus Arg-Gly-Asp motif, and having binding activity for  $\alpha\text{v}\beta 3$ ,  $\alpha\text{v}\beta 5$ , or  $\alpha 9\beta 1$  integrin. The present specification and Nakamura et al, 2000 provide written description for such a polypeptide and therefore this rejection is overcome.

These arguments are not found to be persuasive for the following reasons. It is acknowledged that Claim 1 is so amended. However, neither the specification nor the prior art described the genus of any polypeptide having at least 90% identity to SEQ ID NO: 6, wherein the polypeptide binds to any protein having  $\alpha\text{v}\beta 3$ ,  $\alpha\text{v}\beta 5$ , or  $\alpha 9\beta 1$  integrin activity in a manner such that the skilled artisan would recognize that Applicants were in possession of said genus. The family of integrins, including  $\alpha\text{v}\beta 3$ ,  $\alpha\text{v}\beta 5$ , or  $\alpha 9\beta 1$ , are structurally and functionally diverse

(van der Flier et al, 2001). Claims 1, 2, and 35 encompasses a genus of polypeptides capable of binding to any protein having any structure and any activity of any  $\alpha v\beta 3$ ,  $\alpha v\beta 5$ , or  $\alpha 9\beta 1$  integrin. The specification fails to describe said genus such that the skilled artisan would recognize that Applicants were in possession of the recited invention.

For these reasons and those explained in the prior action, rejection of Claims 1, 2, and 35 are rejected under 35 U.S.C. 112, first paragraph/written description, is maintained.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Rejection of Claims 1, 2, and 35 under 35 U.S.C. 103(a) as being unpatentable over Kowal et al, 1999 is withdrawn for the following reasons. In support of their request that said rejection be withdrawn, Applicants argue that the current limitation of Claim 1 requires 90% or more amino acid sequence identity to the full length amino acid sequence of SEQ ID NO: 6. This argument is found to be persuasive for the following reasons. The specific fragment of Kowal's protein, representing residues 23-77 thereof, has 96% identity with SEQ ID NO: 6 and comprises an RGD motif. However, there is no motivation to make said specific fragment. Therefore, rejection of Claims 1, 2, and 35 under 35 U.S.C. 103(a) as being unpatentable over Kowal et al, 1999 is withdrawn.

***Allowable Subject Matter***

No claims are allowable.

Applicant's amendment necessitated any new grounds of rejection presented in this Office action. Any new references were cited solely to support rejection(s) based on amendment or rebut Applicants' arguments. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Regarding filing an Appeal, Applicants are referred to the Official Gazette Notice published July 12, 2005 describing the Pre-Appeal Brief Review Program.

#### **Final Comments**

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages. It is also requested that the serial number of the application and date of amendment be referenced on every page of the response.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/  
Primary Examiner, Art Unit 1652